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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,086	07/06/2007	Valery Rubinchik	249692001800	5458

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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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06/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,086	Applicant(s) RUBINCHIK ET AL.	
	Examiner Ahmed M. Farah	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/30/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

(Presence of possible 112, sixth paragraph, limitations)

Claim 18 is objected to because of the following informalities: the claim recites the term that the light is delivered "by means of" a laser, optical fiber, or combination thereof in lines 1-2. It is not clear to the examiner whether the applicants want to invoke the 35 U.S.C. 112, sixth paragraph.

When it is not clear whether a claim limitation should be treated under 35 U.S.C. 112, sixth paragraph, determining the patentability of that claim is difficult because the scope of the claim and the relevance of the prior art cannot be readily determined. Applicants have an opportunity and obligation to define their inventions precisely during proceedings before the PTO. They are required to specify their inventions, consistent with the guidelines described in MPEP 2181, when a claim limitation invokes 35 U.S.C. 112, sixth paragraph.

A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for";
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

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If the applicants wish to have the claim limitations under 112, sixth paragraph interpretation, they must: show why the claim language properly invokes 35 U.S.C. 112, sixth paragraph; identify the function; and identify the corresponding structure. They must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112 , sixth paragraph. See *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim recites that the distal end of the guide-wire is "pre-positioned in the bladder" of the patient. One cannot positively recite or claim any portion of a human body.

Correction, such as a step of --pre-positioning the guide-wire in the bladder-- is suggested.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the peak concentration" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the peak concentration" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the peak concentration" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Selman Pub. No.: US 2002/0193850 in view of Chen et al. Pub. NO.: US

2003/0167033.

Selman discloses apparatus and methods of use for photodynamic therapy of prostatic tissue, comprising: administering an effective amount of photosensitizing agent to the prostate tissue of a patient; and irradiation the prostate tissue with EM energy of sufficient energy to active the photosensitizer. The apparatus comprises a catheter device having an inflatable balloon disposed at the distal end of the catheter as claimed, with the exception of a guide-wire.

However, the use of guide-wire for guiding a treatment catheter is known in the art. Chen et al. disclose an alternative catheter apparatus and methods of use for photodynamic therapy of body tissue, such as prostatic tissue (see Fig. 7), the apparatus comprising a guide-wire 36 adapted to guide the catheter to the desired treatment site. Therefore, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify Selman in view of Chen et al. to use a guide-wire in order to direct/guide the catheter to the desired treatment site as claimed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US. Patent No. 5,456,661 to Narciso, Jr. discloses a catheter device and method of use for photodynamic therapy of prostatic tissue, the catheter device comprising: a guide-wire, energy delivery optical fiber, and an inflation balloon (see Figs. 3 and 4, and claims 1-4).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johnson Henry can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/
Primary Examiner, Art Unit 3769

June 21, 2009.